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भारतीय मानक

चिकित्सीय विद्युत उपस्कर

भाग 1 सुरक्षा के लिए सामान्य अपेक्षाएँ

अनुभाग 1 सामांन्तर मानक — चिकित्सीय विद्युत प्रणाली के लिए सुरक्षा जरुरतें

Indian Standard

MEDICAL ELECTRICAL EQUIPMENT

PART 1 GENERAL REQUIREMENTS FOR SAFETY

Section 1 Collateral Standard — Safety Requirements for Medical Electrical System

ICS 11.040.01

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BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

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AMENDMENT NO.1 NOVEMBER 2008
TO
IS 13450 (PART 1/Sec 1) : 2006/IEC 60601-1-1(2000)
MEDICAL ELECTRICAL EQUIPMENT

[*National Foreword*, *Last Paragraph*] — Add the following at the end.

BIS CERTIFICATION MARKING

The product may also be marked with the Standard Mark.

The use of the Standard Mark is governed by the provisions of the '*Bureau of Indian Standards Act*, 1986' and the Rules and Regulations made thereunder. The details of the condition under which the license for the use of Standard Mark may be granted to manufacturers or producers may be obtained from Bureau of Indian Standards.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2:1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be same as that of the specified value in this standard.

(MHR 15)

Reprography Unit, BIS, New Delhi, India

Electromedical Equipment Sectional Committee, MHR 15

NATIONAL FOREWORD

This Indian Standard (Part 1/Sec 1) which is identical with IEC 60601-1-1 (2000) 'Medical electrical equipment — Part 1-1 : General requirements for safety — Collateral standard: Safety requirements for medical electrical systems' issued by the International Electrotechnical Commission (IEC) was adopted by the Bureau of Indian Standards on the recommendation of the Electromedical Equipment Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

The text of the IEC Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.

b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

c) Only the English language text in the International Standard has been retained while adopting it in this Indian Standard and as such the page numbers given here are not the same as in the IEC Publication.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their places are listed below along with their degree of equivalence for the editions indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
IEC 60529 (1989) Degrees of protection provided by enclosures (IP code)	IS 12063 : 1987 Classification of degrees of protection provided by enclosures of electrical equipment	Technically Equivalent
IEC 60884-1 (1994) Plugs and socket-outlets for household and similar purposes — Part 1 : General requirements	IS 1293 : 2005 Plugs and socket-outlets of rated voltage up to and Including 250 volts and rated current up to and including 16 amperes — Specification	do

The technical committee responsible for the preparation of this standard has reviewed the provisions of the following International Standards and has decided that they are acceptable for use in conjunction with this standard:

International Standard	*Title*
IEC/TR3 60083 (1997)[1]	Plugs and socket-outlets for domestic and similar general use standardized in member countries of IEC
IEC 60601-1 (1988)[2]	Medical electrical equipment — Part 1 : General requirements for safety
IEC 60989 (1991)	Separating transformers, autotransformers, variable transformers and reactors

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[1] Information on Indian Plugs and socket-outlets is not given.

[2] Since revised in 2005.

Indian Standard
MEDICAL ELECTRICAL EQUIPMENT
PART 1 GENERAL REQUIREMENTS FOR SAFETY
Section 1 Collateral Standard — Safety Requirements for Medical Electrical System

SECTION ONE — GENERAL

1 Scope and object

*1.201 Scope

This standard applies to the safety of MEDICAL ELECTRICAL SYSTEMS, as defined in 2.201. It describes the safety requirements necessary to provide protection for the PATIENT, the OPERATOR and surroundings.

2 Terminology and definitions

In this Collateral Standard, terms printed in small capitals are used in accordance with their definitions in IEC 60601-1.

Where the terms "voltage" and "current" are used, they mean the r.m.s. values of an alternating, direct or composite voltage or current.

For the purpose of this standard the following additional definitions apply:

2.201
MEDICAL ELECTRICAL SYSTEM (hereinafter referred to as SYSTEM)
combination of items of equipment, at least one of which must be MEDICAL ELECTRICAL EQUIPMENT and inter-connected by FUNCTIONAL CONNECTION or use of a MULTIPLE PORTABLE SOCKET-OUTLET

NOTE Equipment, when mentioned in connection with a SYSTEM, should be taken to include EQUIPMENT. (See also examples given in annexes BBB and FFF.)

***2.202**
PATIENT ENVIRONMENT
any volume in which intentional or unintentional contact can occur between PATIENT and parts of the SYSTEM or between PATIENT and other persons touching parts of the SYSTEM (see figure 201)

***2.203**
SEPARATION DEVICE
a component or arrangement of components with input parts and output parts that, for safety reasons, prevent a transfer of unwanted voltage or current between parts of a SYSTEM

***2.204**
MULTIPLE PORTABLE SOCKET-OUTLET
a combination of two or more socket-outlets intended to be connected to, or integral with, flexible cables or cords, and which can easily be moved from one place to another while connected to the supply

NOTE A MULTIPLE PORTABLE SOCKET-OUTLET may be a separate item or an integral part of medical or non-medical equipment

***2.205**
FUNCTIONAL CONNECTION
connection, electrical or otherwise, including those intended to transfer signals and/or power and/or substances

3 General requirements

*3.201 General requirements for the SYSTEM

After installation or subsequent modification, a SYSTEM shall not cause a SAFETY HAZARD.

A SYSTEM shall provide:

- within the PATIENT ENVIRONMENT, a level of safety comparable to that provided by MEDICAL ELECTRICAL EQUIPMENT complying with IEC 60601-1, and
- outside the PATIENT ENVIRONMENT, the level of safety appropriate for non-medical electrical equipment complying with other IEC or ISO safety standards.

Compliance is considered to exist if the requirements of 3.201.1, 3.201.2, 3.201.3 and 3.201.4 are met. A SYSTEM incorporating equipment or parts, which use materials or have forms of construction different from those detailed in relevant standards as mentioned in 3.201.1 and 3.201.2, shall be accepted if it can be demonstrated that an equivalent degree of safety is obtained.

3.201.1 MEDICAL ELECTRICAL EQUIPMENT

MEDICAL ELECTRICAL EQUIPMENT shall comply with the requirements of IEC 60601-1 and its relevant particular standards.

Compliance is checked by inspection of appropriate documents or certificates.

3.201.2 Non-medical electrical equipment

Non-medical electrical equipment shall comply with IEC and ISO safety standards that are relevant to that equipment. See also annex DDD.

Equipment in which protection against electric shock relies on BASIC INSULATION only shall not be used in a SYSTEM.

Compliance is checked by inspection of appropriate documents or certificates.

*3.201.3. Specified power supply

A specified power supply according to 10.2.2.201 shall be in accordance with IEC 60601-1 or shall demonstrate an equivalent degree of safety.

NOTE The party assembling or modifying the SYSTEM should calculate the power consumption of the SYSTEM, make sure that this consumption is consistent with the power that the MULTIPLE PORTABLE SOCKET-OUTLET(S) can support and document it.

Compliance is checked by inspection of appropriate documents or certificates.

*3.201.4. SYSTEM

After installation or subsequent modification, the SYSTEM shall be in compliance with the requirements of this Collateral Standard.

Compliance is checked by inspection, by testing or by analysis, as specified in the relevant subclause.

Only hazards arising from the interconnection of various equipment to constitute a SYSTEM *shall be considered.*

Safety tests which have already been carried out on individual equipment of the SYSTEM *according to relevant standards shall not be repeated.*

Tests shall be carried out:

- *in* NORMAL CONDITION *unless otherwise specified in this standard, and*
- *under the operating conditions specified by the manufacturer of the* SYSTEM.

6 Identification, marking and documents

*6.8.201 ACCOMPANYING DOCUMENTS of a SYSTEM

A SYSTEM (including a modified SYSTEM) shall be accompanied by documents containing all the data necessary for safe and intended use.

These documents shall include:

a) the ACCOMPANYING DOCUMENTS for each item of MEDICAL ELECTRICAL EQUIPMENT (see 6.8 of IEC 60601-1);

b) the equivalent documents for each item of non-medical electrical equipment;

c) the following information:

- instructions for cleaning and, where applicable, sterilizing and disinfecting each item of equipment forming part of the SYSTEM;
- additional safety measures which should be applied, during installation of the SYSTEM;
- which parts of the SYSTEM are suitable for use within the PATIENT ENVIRONMENT;
- additional measures which should be applied during preventive maintenance;
- a warning that MULTIPLE PORTABLE SOCKET-OUTLETS shall not be placed on the floor;
- a warning that an additional MULTIPLE PORTABLE SOCKET-OUTLET or extension cord shall not be connected to the system;
- a warning not to connect items which are not specified as part of the SYSTEM;
- the maximum permitted load for any MULTIPLE PORTABLE SOCKET-OUTLET(S) used with the SYSTEM;
- an instruction that MULTIPLE PORTABLE SOCKET-OUTLETS provided with the SYSTEM shall only be used for supplying power to equipment which is intended to form part of the SYSTEM;
- an explanation of the risks of connecting a non-medical electrical equipment, which has been supplied as a part of the SYSTEM, directly to the wall outlet when the non-medical equipment is intended to be supplied via a MULTIPLE PORTABLE SOCKET-OUTLET with a separating transformer;

- an explanation of the risks of connecting electrical equipment, which has not been supplied as a part of the SYSTEM, to the MULTIPLE PORTABLE SOCKET-OUTLET;
- any restrictions in the environmental conditions to ensure safety (see clause 10 of the General Standard);
- instructions to the OPERATOR not to touch parts referred to in 16.201 and the PATIENT simultaneously;

d) advice to

- the installer, recommending that the SYSTEM be installed in a way that enables the USER to achieve optimal use, and
- the USER, to carry out all cleaning, adjustment, sterilization and disinfection procedures specified herein.

Compliance is checked by inspection.

SECTION TWO — ENVIRONMENTAL CONDITIONS

10 Environmental conditions

*10.2.2.201 Power supply

A power supply from another equipment for EQUIPMENT in a SYSTEM shall be specified by the manufacturer.

SECTION THREE — PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

16 ENCLOSURES and PROTECTIVE COVERS

16.201 ENCLOSURES

Parts of non-medical electrical equipment in the PATIENT ENVIRONMENT that, after removal of covers, connectors, etc., without the use of a TOOL, may be contacted by the OPERATOR during routine maintenance, calibration, etc., shall operate at a voltage not exceeding 25 V a.c. or 60 V d.c. or peak value supplied from a source which is separated from the SUPPLY MAINS by one of the methods described in 17 *g)* 1) to 5) of IEC 60601-1.

Compliance is checked by inspection.

17 Separation

*17.201 Electrical separation

If the allowable values of LEAKAGE CURRENTS can be exceeded – caused by FUNCTIONAL CONNECTION between different items of equipment of a SYSTEM and other systems, for example, an emergency calling system or a data processing system – then safety measures incorporating a SEPARATION DEVICE shall be applied.

Such safety measures provide suitable electrical separation between the equipment and/or between the SYSTEM and other systems and shall have the dielectric strength, CREEPAGE

DISTANCES and AIR CLEARANCES appropriate for the highest voltage occurring across the SEPARATION DEVICE during a fault condition.

Compliance is checked as follows:

The SEPARATION DEVICE shall withstand the dielectric strength test for BASIC INSULATION according to clause 20 of IEC 60601-1 between input parts and output parts. The terminals of each of these parts are connected together during the test.

The test voltage is chosen from table V of IEC 60601-1.

The reference voltage (U) is the highest RATED supply voltage or, for polyphase equipment, the phase-to-neutral supply voltage. For INTERNALLY POWERED EQUIPMENT, U is 250 V a.c.

19 Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

*19.201 LEAKAGE CURRENTS

19.201.1 ENCLOSURE LEAKAGE CURRENT

In NORMAL CONDITION, the ENCLOSURE LEAKAGE CURRENT from or between parts of the SYSTEM within the PATIENT ENVIRONMENT shall not exceed 0,1 mA.

NOTE For the purpose of this standard, the LEAKAGE CURRENT from accessible outer surfaces of equipment is also considered to be ENCLOSURE LEAKAGE CURRENT.

In the event of the interruption of any non-permanently installed PROTECTIVE EARTH CONDUCTOR or the equivalent conductor of a MULTIPLE PORTABLE SOCKET-OUTLET or of an equipment, the ENCLOSURE LEAKAGE CURRENT from or between parts of a SYSTEM within the PATIENT ENVIRONMENT shall not exceed 0,5 mA.

If the SYSTEM or part of the SYSTEM is supplied from a MULTIPLE PORTABLE SOCKET-OUTLET, then the current in the PROTECTIVE EARTH CONDUCTOR of the MULTIPLE PORTABLE SOCKET-OUTLET shall not exceed 0,5 mA.

19.201.2 PATIENT LEAKAGE CURRENT

In NORMAL CONDITION, the PATIENT LEAKAGE CURRENT shall not exceed 0,1 mA for TYPE B and BF APPLIED PARTS and 0,01 mA for TYPE CF APPLIED PARTS.

Compliance with the requirements of 19.201.1 and 19.201.2 is checked by inspection and measurement of LEAKAGE CURRENTS using a measuring device as specified in 19.4e) of IEC 60601-1.

19.201.3 Connection of SIGNAL INPUT PARTS or SIGNAL OUTPUT PARTS

If compliance of the MEDICAL ELECTRICAL EQUIPMENT with 19.2 *b)* first dash and/or 19.2 *c)* of IEC 60601-1 is achieved by specifying that the SIGNAL INPUT PART and/or SIGNAL OUTPUT PART is for exclusive connection to equipment as specified in the ACCOMPANYING DOCUMENTS, then the SIGNAL INPUT PART and/or SIGNAL OUTPUT PART shall be connected to the specified equipment. However, for CLASS I EQUIPMENT, if the specified equipment is not connected to the common protective earth of the SYSTEM, then a SEPARATION DEVICE shall be used (see situation 3 of table BBB.201).

Compliance is checked by inspection.

SECTION FOUR — PROTECTION AGAINST MECHANICAL HAZARDS

22 Moving parts

22.7.201 Protective means

When movement of parts of a SYSTEM can cause a SAFETY HAZARD, the SYSTEM shall be provided with a protective means, for example, an emergency stopping device, in accordance with 22.7 of IEC 60601-1.

Compliance is checked by inspection.

SECTION FIVE — PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

SECTION SIX — PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES

NOTE See 44.7.201

SECTION SEVEN — PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection and compatibility

*44.7.201 Cleaning, sterilization and disinfection

See informative note in annex AAA.

49 Interruption of the power supply

*49.201 Interruption of the power supply

A SYSTEM shall be so designed that an interruption and restoration of the power supply to any EQUIPMENT or non-medical equipment of the SYSTEM shall not result in a SAFETY HAZARD other than interruption or cessation of its intended function.

Compliance is checked by interruption and restoration of relevant power supplies one at a time.

SECTION EIGHT — ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT

SECTION NINE — ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

52 Abnormal operation and fault conditions

52.1.201

NOTE Requirements for prevention of functional hazards arising from programmable electrical medical systems are specified in IEC 60601-1-4. Attention should be paid to the possible impact of, for example, telematics.

SECTION TEN — CONSTRUCTIONAL REQUIREMENTS

56 Components and general assembly

56.3.201 Connections

Design and construction of electrical, hydraulic, pneumatic and gas connection terminals and connectors shall be such that incorrect connection of accessible connectors, removable without the use of a TOOL, shall be prevented where a SAFETY HAZARD can be caused.

- Connectors shall comply with 17 *g)* of the General Standard.
- Plugs for connection of PATIENT CIRCUIT leads shall be so designed that they cannot be connected to other outlets of the same SYSTEM, which are likely to be located in the PATIENT ENVIRONMENT, unless it can be proven that no SAFETY HAZARD can result.

Compliance is checked by inspection, if possible by interchanging connectors, to establish the absence of a SAFETY HAZARD (LEAKAGE CURRENT exceeding the values in NORMAL CONDITION, movement, temperature, radiation, etc.).

57 MAINS PARTS, components and layout

57.2 MAINS CONNECTORS, APPLIANCE INLETS and the like

NOTE The MAINS CONNECTOR is not required to be fixed since the intent is to prevent unintentional connection of other equipment which may adversely effect the safety of the system. Reassignment of system wiring is a dangerous practice and beyond the scope of this Collateral Standard. Warnings are already provided in 6.8.201.

*57.2.201 MULTIPLE PORTABLE SOCKET-OUTLET

Connection of equipment used in medical practice to a MULTIPLE PORTABLE SOCKET-OUTLET shall only be possible by using a TOOL, or the MULTIPLE PORTABLE SOCKET-OUTLET shall be supplied via a separating transformer.

Compliance is checked by inspection.

The separating transformer and the MULTIPLE PORTABLE SOCKET-OUTLET shall comply with the requirements as given in annex EEE.

57.10 CREEPAGE DISTANCES and AIR CLEARANCES

57.10.201 SEPARATION DEVICE

The SEPARATION DEVICE shall have CREEPAGE DISTANCES and AIR CLEARANCES according to Table 201.

The reference voltage *(U)* is the highest RATED supply voltage or, for polyphase equipment, the phase-to-neutral supply voltage. For INTERNALLY POWERED EQUIPMENT, *U* is 250 V a.c.

Table 201 – CREEPAGE DISTANCE and AIR CLEARANCES for SEPARATION DEVICE in millimetres

U	d.c.	15	36	75	150	300	450	600	800	900	1 200
V	a.c.	12	30	60	125	250	400	500	660	750	1 000
AIR CLEARANCES		0,8	1	1,2	1.6	2,5	3,5	4,5	6	6,5	9
CREEPAGE DISTANCES		1,7	2	2,3	3	4	6	8	10,5	12	16

NOTE The origin of this table is table XVI for BASIC INSULATION or SUPPLEMENTARY INSULATION of IEC 60601-1, and amendments 1 and 2.

Compliance is checked by inspection.

58 Protective earthing – Terminals and connection

*58.201 Protective earthing of SYSTEMS

The connection for protective earthing shall be made so that the removal of any single item of equipment in the SYSTEM will not interrupt the protective earthing of any part of the SYSTEM, without at the same time disconnecting the electrical supply to that part.

All PROTECTIVE EARTH CONDUCTORS and the power supply cord shall be routed together.

Any additional PROTECTIVE EARTH CONDUCTOR shall be permanently connected to a non-mobile item of the SYSTEM and only detachable by use of a TOOL.

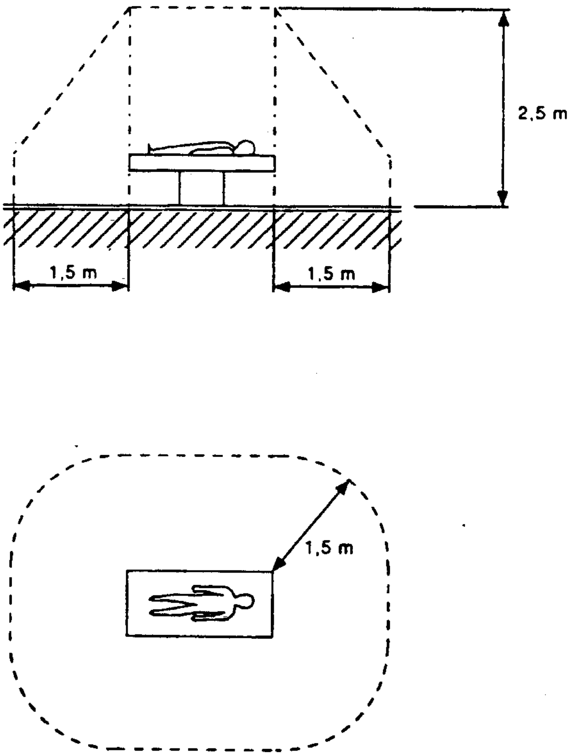
Compliance is checked by inspection.

59 Construction and layout

59.201 Protection of wiring

Conductors, which connect different items of equipment within a SYSTEM shall be protected against mechanical damage.

Compliance is checked by inspection.



NOTE Dimensions shown are not prescriptive.

Figure 201 – Example of PATIENT ENVIRONMENT

Annex AAA
(informative)

General guidance and rationale

Subclause 1.201 Scope

This standard is intended to be used by manufacturers who assemble and offer for sale a combination of electrical equipment which includes one or more items of MEDICAL ELECTRICAL EQUIPMENT. The equipment may be separate items or may be in a single enclosure or a combination of these cases.

This standard is also intended to be used by personnel from institutions for medical practice who assemble such systems. In this case, engineering expertise in the application of the electrical equipment design standards may be required to ensure that the SYSTEM complies with all requirements of this standard.

The application and rapid development of modern electronic and biomedical technologies in medical practice have already led to a situation that instead of a single item of MEDICAL ELECTRICAL EQUIPMENT, rather complex and extensive SYSTEMS of electrical equipment are applied for the diagnosis, therapy and monitoring of PATIENTS.

More and more such SYSTEMS comprise equipment originally manufactured for use in different specific application fields, not necessarily medical, and that are connected with each other in a direct or indirect way. MEDICAL ELECTRICAL EQUIPMENT complying with IEC 60601-1 may be connected with other, non-medical electrical equipment. The latter equipment may, each individually, fully meet the requirements as mentioned in safety standards applicable in their specific application field. They do not always comply with the safety requirements for MEDICAL ELECTRICAL EQUIPMENT and, thereby, influence the safety of the whole SYSTEM.

The electrical equipment may be situated either in a medically used room that is intended for diagnosis, treatment or monitoring of PATIENTS, or in a non-medically used room where no medical practice is carried out. Within a medically used room, electrical equipment may be placed inside or outside a volume that is defined as PATIENT ENVIRONMENT.

There are two situations possible in medical practice.

a) Where this Collateral Standard does not apply

Simultaneously operated MEDICAL ELECTRICAL EQUIPMENT, i.e., different MEDICAL ELECTRICAL EQUIPMENT connected at the same time to a PATIENT but not connected to each other. Such MEDICAL ELECTRICAL EQUIPMENT can influence each other for example, high-frequency surgical equipment in the operating theatre may influence PATIENT monitoring.

NOTE Assistance can be available from the instructions for use for each MEDICAL ELECTRICAL EQUIPMENT.

b) Where this Collateral Standard applies

SYSTEMS, consisting of MEDICAL ELECTRICAL EQUIPMENT and possibly also non-medical electrical equipment, interconnected permanently or temporarily for a certain purpose such as diagnosis or treatment of a PATIENT. Examples: SYSTEMS for diagnostic X-ray examination, endoscopes with video camera, PATIENT monitoring, ultrasound equipment with a personal computer, computed tomography or magnetic resonance imaging.

The various parts of such a SYSTEM may be situated within the PATIENT ENVIRONMENT or outside it but still within a medically used room or may be located in a non-medically used room containing, for example, electrical power distribution or data processing equipment.

Subclause 2.201 MEDICAL ELECTRICAL SYSTEM

Rationale for permitting the use of a MULTIPLE PORTABLE SOCKET-OUTLET in a SYSTEM.

To minimize the impairment of the safety level of IEC 60601-1, the connection of MULTIPLE PORTABLE SOCKET-OUTLET to the SUPPLY MAINS is subject to certain conditions. An additional subclause 57.2.201 requires that MULTIPLE PORTABLE SOCKET-OUTLETS are constructed to comply with the IEC 60601-1 requirements applying to MEDICAL ELECTRICAL EQUIPMENT.

Subclause 2.202 PATIENT ENVIRONMENT

It is difficult to apply unique dimensions to the volume in which diagnosis, monitoring or treatment occurs. The dimensions for the PATIENT ENVIRONMENT given in figure 201 have been justified in practice.

Subclause 2.203 SEPARATION DEVICE

Assembly of equipment into a SYSTEM may involve connections which transfer power and/or signals. In such a case the same separation requirements are needed.

Subclause 2.204 MULTIPLE PORTABLE SOCKET-OUTLETS

The definition is derived from IEC 60884-1.

MULTIPLE PORTABLE SOCKET-OUTLETS are sometimes necessary and offer advantages and disadvantages, which have to be investigated in order to establish a balance.

MULTIPLE PORTABLE SOCKET-OUTLETS may be necessary for the following reasons:

- to minimize the number of power supply cords lying on the floor;
- to allow all the equipment necessary for proper treatment or diagnosis to be used despite an insufficient number of FIXED MAINS SOCKET-OUTLETS;
- to improve mobility having all equipment on one trolley;
- to reduce potential differences within the protective earth wiring to below those which occur in some fixed installations.

The use of MULTIPLE PORTABLE SOCKET-OUTLETS should be avoided as far as possible for the following reasons:

- combined EARTH LEAKAGE CURRENTS may result in
  - excessive earth leakage current in normal condition,
  - excessive enclosure leakage current in the single fault condition of the broken protective earth conductor of the multiple portable socket-outlet supply cable;
- availability of the SUPPLY MAINS depends on the reliability of a single FIXED MAINS SOCKET-OUTLET;
- a complete interruption of electrical supply is possible and may require a long set-up time to reactivate the complete SYSTEM;
- only one protective earth connection to the electrical installation is provided; this is less reliable than when each part of the SYSTEM is directly earthed;
- the protective earth resistance is increased.

The optimum solution is, obviously, to install an adequate number of FIXED MAINS SOCKET-OUTLETS according to appropriate installation rules.

Subclause 2.205 FUNCTIONAL CONNECTION

In the definition of a MEDICAL ELECTRICAL SYSTEM, the FUNCTIONAL CONNECTION is included to allow non-medical electrical equipment to supply power to MEDICAL ELECTRICAL EQUIPMENT. This power supply is restricted by the requirements in this Collateral Standard (see 3.201.3 and 10.2.2.201).

The phrase “or otherwise” may include mechanical, optical or wireless connections, for example.

Subclause 3.201 General requirements for the SYSTEM

Appropriate documentation concerning the standards compliance may be a declaration of conformity by the manufacturer or a certificate from a test house.

Subclause 3.201.3 Specified power supply

Safety after assembly is maintained, for example, by one or more of the following measures:

- measures that are built-in within the MEDICAL ELECTRICAL EQUIPMENT, for example, separation of relevant circuits;
- SEPARATION DEVICES provided as ACCESSORIES to the MEDICAL ELECTRICAL EQUIPMENT (see 17.201);
- SEPARATION DEVICES provided as ACCESSORIES to the SYSTEM;
- separation transformer;
- additional PROTECTIVE EARTH CONDUCTORS.

Non-medical electrical equipment may provide the specified power supply for MEDICAL ELECTRICAL EQUIPMENT in accordance with 4.7*g)*, 6.8.2*h)*, 19.1*c)* and figure 17 of IEC 60601-1. The specified power supply must fulfil the requirements of IEC 60601-1 or demonstrate an equivalent degree of safety is obtained as accepted by 3.4 of IEC 60601-1. See IEC 60513 for guidance.

Subclause 3.201.4 SYSTEM

SYSTEMS, by their nature, are frequently modified; this Collateral Standard does not include the modification of individual items in a SYSTEM.

Subclause 6.8.201 ACCOMPANYING DOCUMENTS of a SYSTEM

The documents that accompany a SYSTEM intended for DIRECT CARDIAC APPLICATION should provide data on such items as

- use of rubber gloves;
- use of stopcocks made of insulating material;
- minimum distances between PATIENT and equipment being part of the SYSTEM (PATIENT ENVIRONMENT);
- instructions about how to use the MEDICAL ELECTRICAL EQUIPMENT in the typical medical application, for example, use of a catheter.

For safety reasons, particular attention should be paid to the different levels of hazards when, within the PATIENT ENVIRONMENT, electrodes or other body sensors are used on the PATIENT, externally and internally, including direct connections to the heart.

Possible connections to the heart of a PATIENT should be kept isolated from the equipment.

The warning not to place MULTIPLE PORTABLE SOCKET-OUTLETS on the floor is to prevent the ingress of liquids and to prevent mechanical damage.

Furthermore, measures should be taken to ensure that, when assembling or modifying a SYSTEM incorporating MULTIPLE PORTABLE SOCKET-OUTLETS, these are mounted in such a way as to prevent ingress of liquids and to avoid mechanical damage during NORMAL USE and transportation.

Relevant safety standards for non-medical electrical equipment may require smaller ranges of environmental conditions than those defined in 10.2 of IEC 60601-1. If such non-medical electrical equipment in a SYSTEM operates under the wider environmental ranges of 10.2, a SAFETY HAZARD can arise and restrictions to the environmental conditions for the SYSTEM or part of the SYSTEM compared with IEC 60601-1 should be described in the documents which accompany the SYSTEM.

Subclause 10.2.2.201 Power supply

This requirement is to ensure the safety level according to IEC 60601-1 at the SYSTEM level.

Subclause 17.201 Electrical separation

The safety of some MEDICAL ELECTRICAL EQUIPMENT depends on the precondition that any SIGNAL INPUT PARTS or SIGNAL OUTPUT PARTS are connected only to equipment which is specified for this purpose, otherwise LEAKAGE CURRENTS may be increased by unwanted currents flowing through signal cables.

Hazardous situations may occur if the SIGNAL INPUT PART or SIGNAL OUTPUT PART of MEDICAL ELECTRICAL EQUIPMENT is connected to equipment outside the medically used room, possibly in another building and therefore connected to another mains supply branch circuit.

A SEPARATION DEVICE prevents a hazard to the PATIENT or OPERATOR. It should be placed as near as practicable to the MEDICAL ELECTRICAL EQUIPMENT. Additionally, the inclusion of the SEPARATION DEVICE helps to avoid hazards through malfunction of equipment caused by unwanted currents flowing through cables.

The need for a SEPARATION DEVICE depends on the configuration of the SYSTEM.

Subclause 19.201 LEAKAGE CURRENTS

Relevant standards for some non-medical electrical equipment may have limits for ENCLOSURE LEAKAGE CURRENTS higher than required by this Collateral Standard; these higher limits are acceptable only outside the PATIENT ENVIRONMENT. It is essential to reduce ENCLOSURE LEAKAGE CURRENTS when non-medical electrical equipment is to be used within the PATIENT ENVIRONMENT. LEAKAGE CURRENT reduction measures may include

- additional protectively earthed parts;
- a separating transformer;
- an additional non-conductive ENCLOSURE.

Interconnecting cables and their connector housings are parts of the ENCLOSURE and therefore the leakage current limits within the PATIENT ENVIRONMENT, as required in 19.201.1, are applicable.

If a MULTIPLE PORTABLE SOCKET-OUTLET without a separation transformer is used, the interruption of its protective earthing may result in ENCLOSURE LEAKAGE CURRENTS equal to the sum of the individual EARTH LEAKAGE CURRENTS.

Subclause 44.7.201 Cleaning, sterilization and disinfection

SYSTEMS should be installed in such a way that the USER is able to carry out the necessary cleaning and, where applicable, the sterilization and disinfection measures as specified in the documents which accompany the SYSTEM. National authorities may require the use of certain sterilization or disinfection methods and measures for protection against hazards of ignition of flammable anaesthetic mixtures.

Subclause 49.201 Interruption of the power supply

Attention should be paid to the effects of interruptions causing unplanned movements, removal of compression forces, and the safe removal of PATIENTS from the PATIENT ENVIRONMENT when a hazardous situation occurs.

Subclause 57.2.201 MULTIPLE PORTABLE SOCKET-OUTLET

Excessive ENCLOSURE LEAKAGE CURRENTS can occur unless casual access for additional equipment connections is impeded or prevented.

Subclause 58.201 Protective earthing of SYSTEMS

Within the PATIENT ENVIRONMENT it is important to limit potential differences between different parts of a SYSTEM, and an adequate connection with a protective earthing system plays an important role in limiting that potential difference. It is therefore important to prevent interruption of that protective means to any part of the SYSTEM.

- The additional protective earthing could be used when the ENCLOSURE LEAKAGE CURRENT in SINGLE FAULT CONDITION exceeds the allowable limits.

- The additional protective earthing is not necessary for MEDICAL ELECTRICAL EQUIPMENT complying with IEC 60601-1. However, in the case of non-medical electrical equipment this will prevent ENCLOSURE LEAKAGE CURRENTS exceeding allowable limits.
- The use of a TOOL is not required to disconnect the mains plug because the mains plug will disconnect both the mains and the protective earth.

Annex BBB
(informative)

Examples of combinations of MEDICAL ELECTRICAL EQUIPMENT and non-medical electrical equipment

BBB.1 Introduction

A summary is given of situations that may occur when different combinations of equipment are used in various medical environments. To keep this summary short, no more than two items of equipment (A and B) are used per situation.

BBB.2 Localities in a medical environment

The following localities are foreseen (see also figure BBB.201):

- the PATIENT ENVIRONMENT as part of a medically used room;
- a medically used room, excluding the PATIENT ENVIRONMENT;
- the non-medically used room (a room not designed for medical treatment, for example, an office or a storage room).

A protective earth can be dedicated to each locality.

NOTE A potential difference (V) can exist between the protective earths in different localities. In case of an interruption of protective earthing (fault condition) for an equipment in the PATIENT ENVIRONMENT, this potential difference may appear on the ENCLOSURE of the equipment causing a SAFETY HAZARD for the OPERATOR or for the PATIENT if the OPERATOR simultaneously touches the equipment and the PATIENT, or for the PATIENT if the equipment is of TYPE B.

BBB.3 Basic principles

- PATIENTS should only be connected to APPLIED PARTS of EQUIPMENT complying with IEC 60601-1. Other equipment should comply with relevant IEC or ISO Standards.
- In fault condition, the allowable ENCLOSURE LEAKAGE CURRENT is 0,5 mA.
- All equipment complying with the safety standard applicable to the originally intended, non-medical use, herein called IEC XXXXX, and placed in the PATIENT ENVIRONMENT needs measures to limit the ENCLOSURE LEAKAGE CURRENT, if this exceeds the values specified in 19.201.1.

BBB.4 An example

Two items of equipment are placed within the PATIENT ENVIRONMENT (see situation No. 1 in table BBB.201).

There are three possibilities designated as 1a, 1b and 1c:

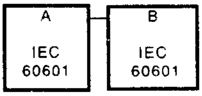
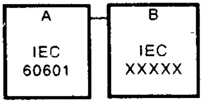
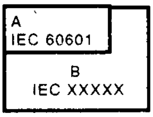
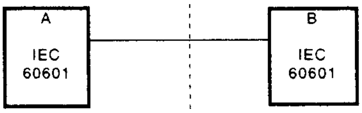
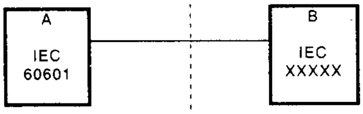
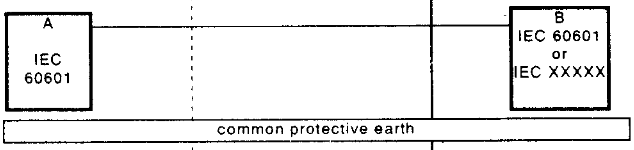
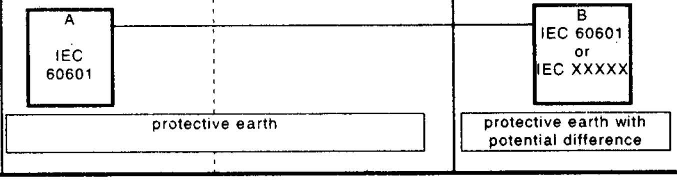
1a: items A and B both comply with IEC 60601: no problems exist;

1b: item A complies with IEC 60601-1 and item B complies with IEC XXXXX: only the ENCLOSURE LEAKAGE CURRENT of item B has to be limited when any single PROTECTIVE EARTH CONDUCTOR or the equivalent conductor of the equipment, is interrupted, if necessary, by applying an additional protective earth or a separating transformer to item B;

1c: item A is powered from a specified power supply in item B. Item B needs the measures for a specified power supply as described by the manufacturer and must fulfil the requirement of 3.201.3. If necessary, apply an additional protective earth or a separating transformer to item B.

NOTE Situations 2 and 3 can be derived from table BBB.201.

Table BBB.201 - Combinations of MEDICAL ELECTRICAL EQUIPMENT and non-medical electrical equipment

Situation No.		Medically used room		Non-medically used room	Feasible solution (See clause 19 in all situations)
		Inside the PATIENT ENVIRONMENT	Outside the PATIENT ENVIRONMENT		
1.	1a Items A and B in PATIENT ENVIRONMENT				
	1b Items A and B in PATIENT ENVIRONMENT				For B: Additional protective earth or separating transformer
	1c Item A powered from specified power supply in item B in PATIENT ENVIRONMENT				For B: Additional protective earth or separating transformer
2.	2a Item A in PATIENT ENVIRONMENT and item B in medically used room				
	2b Item A in PATIENT ENVIRONMENT and item B in medically used room				For B: See 19.201 and its rationale
3.	3a Item A in PATIENT ENVIRONMENT and item B in non-medically used room	 A IEC 60601 B IEC 60601 or IEC XXXXX common protective earth			For B: See 19.201 and its rationale
	3b Item A in PATIENT ENVIRONMENT and item B in non-medically used room	 A IEC 60601 B IEC 60601 or IEC XXXXX protective earth protective earth with potential difference			For B: Additional protective earth or SEPARATION DEVICE

KEY TO TABLE

- Additional protective earth: If necessary, provide additional protective earthing, which is permanently connected (see also 58.201).

  NOTE Equipment modification may be required.

- Separating transformer: If necessary, limit the ENCLOSURE LEAKAGE CURRENT, by using an additional separating transformer according to annex EEE.

  NOTE 1 No equipment modification is required.

  NOTE 2 A separating transformer is a transformer with one or more input winding(s) separated from the output winding(s) by at least basic insulation [IEC 60989].

- SEPARATION DEVICE: If necessary, apply SEPARATION DEVICE.
- IEC 60601: MEDICAL ELECTRICAL EQUIPMENT in compliance with IEC 60601.
- IEC XXXXX: Non-medical equipment in compliance with relevant IEC safety standards.

Annex CCC
(normative)

Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of IEC 60601. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of IEC 60601 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. For undated references, the latest edition of the normative document referred to applies. Members of IEC and ISO maintain registers of currently valid International Standards.

IEC/TR3 60083:1997, *Plugs and socket-outlets for domestic and similar general use standardized in member countries of IEC*

IEC 60529:1989, *Degrees of protection provided by enclosures (IP Code)*

IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*
Amendment 1 (1991)
Amendment 2 (1995)

IEC 60884-1:1994, *Plugs and socket-outlets for household and similar purposes – Part 1: General requirements*
Amendment 1 (1994)
Amendment 2 (1995)

IEC 60989:1991, *Separating transformers, autotransformers, variable transformers and reactors*

NOTE 1 For informative references, see annex DDD.

NOTE 2 For equipment and SYSTEMS, the electrical installation in a medical establishment is an important aspect to consider. In some countries, special requirements apply.

Annex DDD
(informative)

Bibliography

IEC 60065:1998, *Audio, video and similar electronic apparatus – Safety requirements*

IEC 60335-1:1991, *Safety of household and similar electrical appliances – Part 1: General requirements*
Amendment 1(1994)

IEC 60601-1-4:1996, *Medical electrical equipment – Part 1: General requirements for safety – 4. Collateral Standard: Programmable electrical medical systems*
Amendment 1 (1999)

IEC 60825-1:1993, *Safety of laser products – Part 1: Equipment classification, requirements and user's guide*
Amendment 1(1997)*

IEC 60950:1999, *Safety of information technology equipment*

IEC 61010-1:1990, *Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements*
Amendment 1(1992)
Amendment 2 (1995)

ISO 7767:1997, *Oxygen monitors for monitoring patient breathing mixtures – Safety requirements*

ISO 8185:1997, *Humidifiers for medical use – General requirements for humidification systems*

ISO 8359:1996, *Oxygen concentrators for medical use – Safety requirements*

ISO 9918:1993, *Capnometers for use with humans – Requirements*

ISO 10079-1:1991, *Medical suction equipment – Part 1: Electrically powered suction equipment – Safety requirements*

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* There exists a consolidated edition 1.1 (1998) that includes IEC 60825-1 and its amendment 1 (1997).

Annex EEE
(normative)

Requirements for MULTIPLE PORTABLE SOCKET-OUTLETS

EEE.1 MULTIPLE PORTABLE SOCKET-OUTLET with separating transformers

A MULTIPLE PORTABLE SOCKET-OUTLET may be a separate item or an integral part of EQUIPMENT or non-medical electrical equipment.

The separating transformer shall comply with the requirements of IEC 60989, with exception of maximum RATED output power (1 kVA) and degree of protection (IPX4).

NOTE The DOUBLE or REINFORCED INSULATION as required for isolating transformers (for example, IEC 60742) is not required because the ENCLOSURE LEAKAGE CURRENT of the SYSTEM is less than 0,5 mA in SINGLE FAULT CONDITION, therefore a separating transformer is sufficient.

This transformer assembly shall be of class I.

NOTE This requirement is necessary to provide connected equipment with a protective earth connection.

If necessary the transformer assembly shall have a specified degree of protection against ingress of water as detailed in the current edition of IEC 60529.

The RATED output power limit of 1 kVA for the transformer specified in IEC 60989 does not apply.

NOTE Limitation of output power is not explained in IEC 60989 and the RATED output power is defined by the fuse in the installation and by the used allowable power supply cable. However, the characteristics of the transformer will be carefully selected, taking into account the variations in the load current of the SYSTEM to ensure that the MAINS VOLTAGE to the various items of the SYSTEM remains within the limits specified in 10.2.2 of IEC 60601-1.

In addition to the requirements of IEC 60989, the transformer assembly shall be marked according to the requirements of 6.1 and 6.2 of IEC 60601-1.

The MULTIPLE PORTABLE SOCKET-OUTLET shall be marked with the maximum allowed output.

The MULTIPLE PORTABLE SOCKET-OUTLET shall be permanently connected to the transformer or the socket-outlet of the separating transformer assembly shall be of a type that cannot accept mains plugs according to IEC/TR3 60083 (see annex FFF).

NOTE Isolation monitoring of the separating transformer is not necessary. SINGLE FAULT CONDITION can be detected during routine maintenance and double fault condition is of no concern. The transformer construction with protectively earthed centre tapped secondary winding is allowed, but not required.

The MULTIPLE PORTABLE SOCKET-OUTLET shall be marked with symbol 14 of table DI, appendix D of IEC 60601-1.

Compliance is checked by inspection and as described in the relevant subclauses of IEC 60601-1.

EEE.2 MULTIPLE PORTABLE SOCKET-OUTLET

The MULTIPLE PORTABLE SOCKET-OUTLETS shall comply with IEC 60884-1, and as follows:

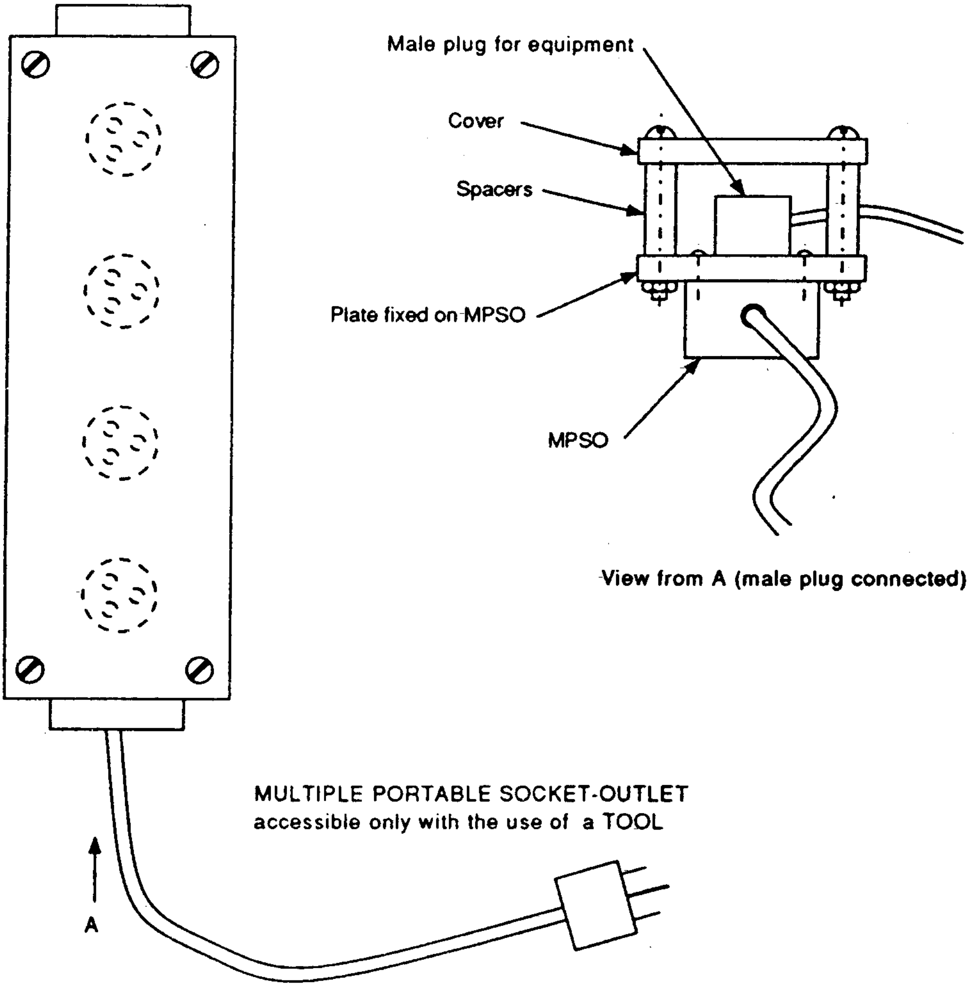
- CREEPAGE DISTANCES and AIR CLEARANCES shall comply with 57.10 of IEC 60601-1.
- The MULTIPLE PORTABLE SOCKET-OUTLETS shall be of class I and the PROTECTIVE EARTH CONDUCTOR shall be connected to the earthing contacts in the output sockets.
- Protective earth terminals and protective earthing connections shall comply with clause 58 of IEC 60601-1.
- ENCLOSURES shall comply with clause 16 of IEC 60601-1.
- MAINS TERMINAL DEVICES and wiring, if applicable, shall comply with 57.5 of IEC 60601-1.
- Ratings of components shall not conflict with the conditions of use (see 56.1 b) of IEC 60601-1).
- Requirements for connections as described in 56.3 of IEC 60601-1 shall be fulfilled.
- Requirements for the power supply cords as described in 57.3 and 57.4 of IEC 60601-1, shall be fulfilled.
- Protective earthing shall comply with clause 18 of IEC 60601-1.

  NOTE The total impedance of the protective earth path for a SYSTEM may be up to 0,4 Ω or higher, if the conditions of 18 *g)* of IEC 60601-1 are satisfied.
- The MULTIPLE PORTABLE SOCKET-OUTLET shall be marked with symbol 14 of table DI, appendix D of IEC 60601-1.

Compliance is checked by inspection and as described in the relevant subclauses of IEC 60601-1.

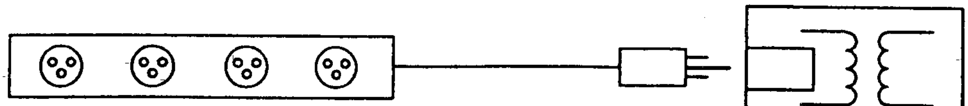
Annex FFF
(informative)

Examples of application of MULTIPLE PORTABLE SOCKET-OUTLETS



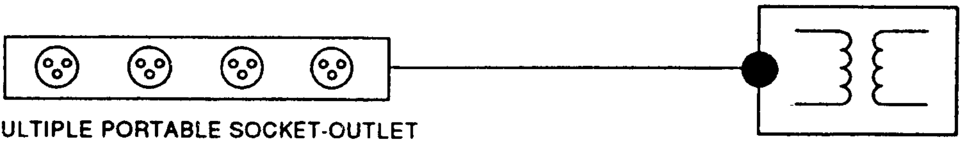
View from A (male plug connected)

MULTIPLE PORTABLE SOCKET-OUTLET
accessible only with the use of a TOOL



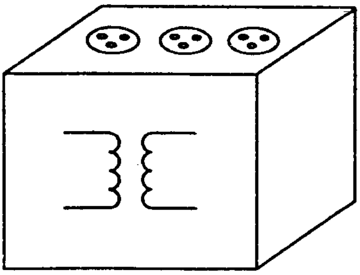
MULTIPLE PORTABLE SOCKET-OUTLET

Transformer assembly with
special socket-outlet

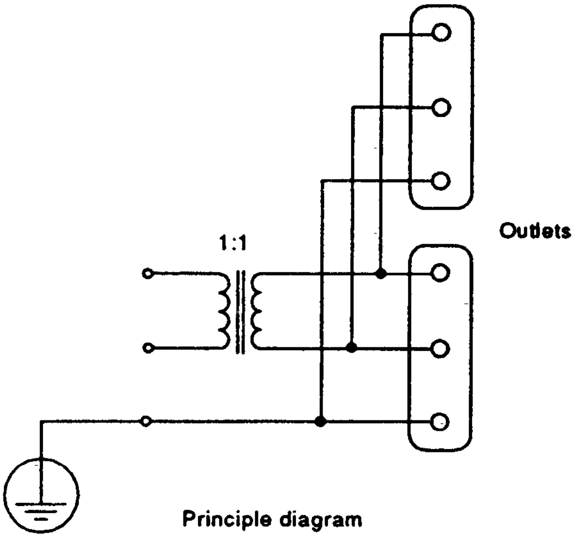


MULTIPLE PORTABLE SOCKET-OUTLET

Transformer assembly with
permanently connected MULTIPLE
PORTABLE SOCKET-OUTLET



Transformer assembly incorporating
MULTIPLE PORTABLE SOCKET-OUTLET



Principle diagram

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